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REMARKS

Claims 1-16 are pending in this application. Claims 1-6 and 8-16 were variously rejected under 35 U.S.C. §112, first paragraph. Claims 1-16 were variously rejected under 35 U.S.C. §112, second paragraph. Claims 1-16 were variously rejected under 35 U.S.C. §102. Claims 1-6, 7, 13, 14, and 16 were variously rejected under the judicially created doctrine of obviousness-type double patenting.

By this amendment, claim 8 has been canceled, claims 1-7 and 9-16 have been amended, and new claim 17 has been added, without prejudice or disclaimer of any previously claimed subject matter. Support for the amendments and new claim can be found, *inter alia*, throughout the specification and the claims as originally filed. For example, support for the amendment to claims 1, 7, 14, and 16 can be found, *inter alia*, at page at page 9, lines 8-9, and in the Abstract of the substitute specification where it is disclosed that the amylin or amylin agonist may be administered "alone or in conjunction with another obesity relief agent." Support for the amendment to claim 15 can be found, for example, at page 24, lines 15-17, and in Table 1 of the substitute specification. Support for new claim 17 can be found, *inter alia*, at page 9, lines 6-8, of the substitute specification.

The amendment is made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all amendments and canceled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover, have not acquiesced to any rejections or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

Objection

The specification was objected to as allegedly including new matter with the amendment filed December 2, 2002. Specifically, the Examiner asserts that the last paragraph on page 32 of

the substitute specification and Examples 9-22 "were not materials specifically identified as being incorporated." Office Action, section 10, page 3. Applicants respectfully disagree with this objection.

The paragraphs objected to are all taken from the contents of the patent application incorporated by reference on page 10 of the substitute specification (page 14 of the original specification). The specification refers directly to the amylin agonist analogs in the referenced application and thus specifically indicates that material related to the amylin agonist analogs is to be incorporated. In particular, Examples 9-20 provide information on the preparation of the specific analogs that are listed in originally filed Table II (see, e.g., substitute specification, page 30, and original specification, page 37).

Although Applicants submit that the last paragraph on page 32 of the substitute specification is properly incorporated from the referenced patent application, the paragraph has herein been removed from the specification in order to facilitate disposition of the present application.

Thus, Applicants respectfully submit that the paragraphs added via the December 2, 2002 amendment are properly incorporated by reference in the originally filed application. Accordingly, Applicants respectfully request reconsideration and withdrawal of the objection to the specification.

Rejections under Obviousness-type Double Patenting

Claims 14 and 16 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 64 and 68 of U.S. Pat. No. 6,956,026 (hereinafter, "the '026 patent"). Claims 7, 14 and 16 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 85 of U.S. Pat. No. 5,739,106 (hereinafter "the '106 patent"). Claims 7, 13, 14 and 16 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 34 and 35 of U.S. Pat. No. 5,686,411 (hereinafter "the '411 patent") as evidenced by Tsanev (*Vutr. Boles* 23:12-17, 1984, abstract). Claims 7, 13, 14 and 16 were rejected under the judicially created doctrine of obviousness-type double patenting as

allegedly being unpatentable over claims 11 and 13 of U.S. Pat. No. 5,321,008 (hereinafter "the '008 patent) as evidenced by Tsanev and the '106 patent. Claims 1-7, 13, 14 and 16 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 33 of co-pending U.S. Pat. Application No. 09/445,517 (hereinafter "the '517 application"). Claims 7, 14 and 16 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 6 of U.S. Pat. Application No. 10/851,574 (hereinafter "the '574 application").

As amended herein, the claimed invention is directed to methods of treating obesity in a human subject through administration of an amylin or an amylin agonist and not in conjunction with administration of another obesity relief agent. The methods are directed to treating obesity in a human subject in need of such treatment and the amount of the composition administered is effective to treat obesity.

The '026 patent

Applicants respectfully traverse this rejection of pending claims 14 and 16 over claims 64 and 68 of the '026 patent.

Relevant to the pending claims, claim 64 of the '026 patent is directed to a method of reducing food intake in a subject comprising administering exendin-4 and an amylin agonist and claim 68 of the '026 patent is directed to a method for reducing appetite in a subject comprising administering exendin-4 and an amylin agonist. The '026 patent demonstrates that administration of exendin-4 alone inhibits food intake. See, for example, Examples 1-4 of the '026 patent.

As noted above, claim 14 is directed to a method of treating obesity through administering a compound selected from the group consisting of an amylin, an amylin agonist, and pharmaceutically acceptable salts thereof, where the composition is not administered in conjunction with another obesity relief agent. Since the cited claims of the '026 patent are directed to the administration of <u>both</u> exendin-4 and an amylin agonist, the cited claims do not teach or suggest the claimed invention. Thus, claims 64 and 68 of the '026 patent do not support

prima facie obviousness with regard to the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

The '106 patent

Applicants respectfully traverse this rejection of pending claims 7, 14 and 16 over claim 85 of the '106 patent.

Claim 85 of the '106 patent is directed to a method for control of body weight in a mammal comprising administering a composition comprising an amylin agonist and a CCK agonist or a composition comprising a hybrid peptide comprising an amylin agonist covalently linked to a CCK agonist. The '106 patent reports that CCK administration was known to inhibit food intake and increase satiety in humans. See, for example, the '106 patent, column 2, lines 43-46.

As noted above, claims 7 and 16 are directed to methods of treating obesity through administering a composition containing an amylin or an amylin agonist as the only obesity relief agent. Claim 14 is directed to a method of treating obesity through administering a compound selected from the group consisting of an amylin, an amylin agonist, and pharmaceutically acceptable salts thereof, where the composition is not administered in conjunction with another obesity relief agent.

Since claim 85 of the '106 patent is directed to the administration of both CCK and an amylin agonist, the cited claim does not teach or suggest the claimed invention. Thus, claim 85 of the '106 patent does not support *prima facie* obviousness with regard to the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

The '411 patent

Applicants respectfully traverse this rejection of pending claims 7, 13, 14 and 16 over claims 34 and 35 of the '411 patent.

Claims 34 and 35 of the '411 patent are directed to methods for the treatment of diabetes mellitus in a mammal comprising the administration to said mammal of a therapeutically effective amount of a particular amylin agonist analogue.

As noted above, claims 7, 13, and 16 are directed to methods of treating obesity in a human subject in need of such treatment through administration of a composition containing an

amylin or an amylin agonist. The amount of the composition administered is effective to treat obesity. Claim 14 is directed to a method of treating obesity through administering a compound selected from the group consisting of an amylin, an amylin agonist, and pharmaceutically acceptable salts thereof, the compound being administered in an amount effective to treat obesity.

The cited claims of the '411 patent are silent with regard to treating obesity. Although obesity is a common among those with diabetes, a claim to treating diabetes mellitus with an amylin agonist analogue does not necessarily teach or suggest treating patients with obesity as claimed. Further, nothing in the cited claims teaches or suggests the use of an amylin or an amylin agonist in an amount effective to treat obesity. Since the cited claims do not teach or suggest treating obesity or the use of an amount effective to treat obesity, a skilled artisan would have no expectation of success for the claimed invention in view of the cited claims. Thus, claims 34 and 35 of the '411 patent do not support *prima facie* obviousness with regard to the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

The '008 patent

Applicants respectfully traverse this rejection of pending claims 7, 13, 14 and 16 over claims 11 and 13 of the '008 patent.

Claim 11 of the '008 patent are directed to a method for the treatment of diabetes mellitus in an insulin-requiring mammal comprising administering to the mammal a therapeutically effective amount of a calcitonin, where the mammal is a human. Claim 13 of the '008 patent is directed to the method of treatment of type II diabetes mellitus comprising the step of administering a therapeutically effective amount of an insulin and a calcitonin where the ratio of insulin to calcitonin from about 100:1 to about 1:2 and is effective to achieve improved glycemic control over insulin therapy alone.

As noted above, claims 7, 13, and 16 are directed to methods of treating obesity in a human subject in need of such treatment through administration of a composition containing an amylin or an amylin agonist. The amount of the composition administered is effective to treat obesity. Claim 14 is directed to a method of treating obesity through administering a compound

selected from the group consisting of an amylin, an amylin agonist, and pharmaceutically acceptable salts thereof, the compound being administered in an amount effective to treat obesity.

The cited claims of the '008 patent are silent with regard to treating obesity. Although obesity is a common among those with diabetes, a claim to treating diabetes mellitus does not necessarily teach or suggest treating patients with obesity as claimed. Further, nothing in the cited claims indicates the use of an amylin or an amylin agonist in an amount effective to treat obesity. Since the cited claims do not teach or suggest treating obesity or the use of an amount effective to treat obesity, a skilled artisan would have no expectation of success for the claimed invention in view of the cited claims. Thus, claims 11 and 13 of the '008 patent do not support *prima facie* obviousness with regard to the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

The '517 and '574 applications

With regard to the provisional rejections, Applicants are willing to consider submitting a terminal disclaimer in the present application with regard to the '517 application and the '574 application should these applications issue as a patent prior to the present application.

In sum, Applicants submit that the pending claims are patentably distinct from the cited claims in the cited patents. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under the judicially created doctrine of obviousness-type double patenting.

Rejections under 35 U.S.C. §112, first paragraph

Claims 1-6 and 8-16 were variously rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims are rejected as allegedly failing to comply with the written description requirement regarding new matter. Applicants respectfully traverse these rejections.

Although Applicants disagree with these new matter rejections and maintain the reasons for traverse already of record, the claims have herein been amended in order to facilitate disposition of the present case.

With regard to the rejection of claim 14 (Office Action, section 40, page 19), the specification describes that the amylin and amylin agonists may form salts that are pharmaceutically acceptable. See, for example, substitute specification, page 20, the paragraph beginning at line 20, and original specification, page 24, the paragraph beginning at line 14. Certainly many of the salts described in the specification, such as acetate, hydrochloride and trifluoroacetate salts, are known in the art to be pharmaceutically acceptable.

With regard to the rejection of claim 15 (Office Action, section 41, page 20), the specification describes a reduction in body weight after four weeks of treatment compared with the body weight prior to treatment. See, for example, Table 1 and the change in body weight from baseline to week 4 in substitute specification, pages 24-25, and original specification, pages 30-31.

With regard to the rejection of claims 1 and 16 (Office Action, section 43, page 21), the specification describes administration of an effective amount of an amylin or an amylin agonist to treat obesity. The specification also describes compositions containing an amylin, an amylin agonist, or pharmaceutically acceptable salts thereof, for use in the claimed methods. See, for example, substitute specification, page 21, line 3, to page 23, line 18, and original specification, page 25, line 3, to page 29, line 2. Thus, taken in its entirety, the specification describes that compositions containing an amylin or amylin agonist are administered in an amount effective to treat obesity.

Applicants note that the specification need not describe the invention using the same words as those used in the claims, as long as the skilled reader understands that the text, taken as a whole, conveys the same meaning. The subject matter of a claim need not be described literally (*i.e.*, use the same terms or *in haec verba*) in order for a disclosure to satisfy the description requirement. M.P.E.P. §§2163, 2163.02.

Applicants submit that the pending claims are fully described in the specification as filed and that the written description requirement has been met. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. 112, first paragraph.

Rejections under 35 U.S.C. §112, second paragraph

Claims 1-16 were variously rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse these rejections.

Although Applicants believe that the claims were sufficiently definite when considered in view of the specification and the understanding of those of skill in the art, Applicants have attempted to respond to the concerns of the Examiner in order to enhance clarity and to facilitate disposition of the present case.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

Rejections under 35 U.S.C. §102

Claims 7, 14 and 16 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by the '026 patent (U.S. Pat. No. 6,956,026). Claims 1-9 and 11-16 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Kolterman *et al.* (*Diabetologia*, 39:492-499, April 1996; hereinafter "Kolterman (1996)"). Claims 1-7, 9-14 and 16 were rejected under 35 U.S.C. §102(a) as allegedly anticipated by Kolterman *et al.* (WO 96/40220; hereinafter "Kolterman ('220)) as evidenced by Tsanev. Applicants respectfully traverse these rejections.

As amended herein, the claimed invention is directed to methods of treating obesity in a human subject through administration of an amylin or an amylin agonist and not in conjunction with administration of another obesity relief agent. The methods are directed to treating obesity in a human subject in need of such treatment and the amount of the composition administered is effective to treat obesity.

The '026 patent

The method of claim 16 recites administration of a composition consisting essentially of an amylin or an amylin agonist. With regard to claim 16, the Examiner states that "claims recited in 'consisting essentially of' language should be construed as if recited in open 'comprising' language, absent some evidence that the additional ingredients in the prior art process/product materially affect the basic and novels characteristics of the claimed invention." The Examiner then asserts that "[t]here is no indication in the instant specification of what is being excluded by" use of the phrase 'consisting essentially of.' Office Action, section 46, page 23. Applicants disagree with this assertion.

The specification states that "[t]he amylin or amylin agonist may be administered alone or in conjunction with another obesity relief agent" at page 9, lines 8-9, of the substitute specification and page 13, lines 4-6, of the original specification. Thus, the specification supports the administration of an amylin or an amylin agonist alone, without another obesity relief agent. The phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps and "those that do not materially affect the basic and novel characteristic(s) of the claimed invention. *In re Hertz*, 190 USPQ 461, 463 (CCPA 1976), original emphasis; M.P.E.P. §2111.03. Thus, a composition consisting essentially of an amylin or an amylin agonist is a composition without another obesity relief agent. Applicants respectfully submit that the specification provides a clear indication as to basic and novel characteristic(s) of the claimed invention and what is being excluded by the language "a composition consisting essentially of an amylin or an amylin agonist."

The '026 patent describes administration of an exendin or an exendin agonist as an appetite suppressant for reducing weight of a subject. The '026 patent also describes administration of the exendin or exendin agonist in conjunction with an amylin or an amylin agonist. The only mention of an amylin or an amylin agonist in the '026 patent is for administration along with exendin. See, for example, the '026 patent, column 5, lines 20-31 and lines 53-59, column 13, lines 25-30, and claims 16, 32, 46, 60, and 68. The '026 patent does not teach the use of an amylin or an amylin agonist alone, not in conjunction with another obesity relief agent.

Since the reference does not teach administration of an amylin or an amylin agonist not in conjunction with another obesity relief agent, *i.e.*, alone, the '026 patent does not teach the claimed methods. Thus, the '026 patent does not anticipate the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §102(e).

Kolterman (1996)

As noted above, the claimed invention is directed to methods of treating obesity in a human subject in need of such treatment through administration of an amylin or an amylin agonist.

Kolterman (1996) describes the use of an amylin agonist, pramlintide, for treating patients with insulin-dependent diabetes mellitus and demonstrates that administration of the amylin agonist significantly reduces postprandial plasma glucose concentrations. Kolterman (1996) does not teach the use of the amylin agonist for treating obesity or demonstrate a reduction in body weight in those patients administered the amylin agonist. Kolterman (1996) is silent with regard to the effect of the amylin agonist on body weight.

The Examiner states that "Kolterman's (1996) patients who were treated with 30 micrograms of subcutaneously administered pramlintide showed a lower body weight of 70.6 ± 2.7 kg compared to the placebo controls whose body weight was about 4.0 kg higher, i.e., 74.5 ± 2.7 kg (see Table 1)." Office Action, section 47, page 25. Applicants respectfully point out that this interpretation of Kolterman (1996) is incorrect.

Table 1 of Kolterman (1996) describes the demographic characteristics of the 84 subjects entering of the study, not completing the study. The subjects are segregated in Table 1 by treatment group to show that the "mean age, weight, duration of diabetes and base-line haemoglobin A_{1C} concentrations were similar for the various groups." See, Kolterman (1996), page 494, paragraph entitled "Demographics." The mean weight listed for the various treatment groups is prior to the 14-day study. Thus, Table 1 does not demonstrate the effect of pramlintide administration on weight loss. Kolterman (1996) does not report the weight of the subjects at the end of the study and nothing in the reference indicates that pramlintide had any effect on the

weight of the subjects. Applicants respectfully submit that Kolterman (1996) does not explicitly teach the claimed methods.

In addition, the Examiner asserts that "Kolterman's (1996) method of subcutaneous administration of pramlintide to a diabetic patient necessarily serves as the instantly claimed method of treating obesity and therefore anticipates the instantly claimed method." Office Action, section 31A, page 11. Applicants disagree with this assertion. The patient population of Kolterman (1996) is not necessarily the same as the claimed subject, *i.e.*, a subject in need of a method of treating obesity. The Examiner has provided no extrinsic evidence to show that these patient populations are one in the same.

Applicants respectfully note that the "fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993); emphasis in original. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the references, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson* 169 F.3d 743, 745 (Fed. Cir. 1999); emphasis added.

The courts have held that the phrase "in need thereof" is meaningful, and that "the claims' recitation of a patient or a human 'in need' gives life and meaning to the preambles' statement of purpose." *Jansen v. Rexall Sundown, Inc.* 342 F.3d 1329, 1333 (Fed. Cir. 2003). Thus, Kolterman (1996) cannot render unpatentable by inherency the subject population of the claimed invention.

A reference which teaches treating type I diabetic patients with an amylin or amylin agonist does not necessarily teach treating patient with obesity. Thus, the claimed invention cannot be recognized by one skilled in the art as inherently taught in the cited reference.

Applicants respectfully submit that Kolterman (1996) does not explicitly or inherently teach the claimed methods. Thus, the cited reference does not anticipate the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §102(b).

Kolterman ('220)

As noted above, the claimed invention is directed to methods of treating obesity in a human subject in need of such treatment through administration of an amylin or an amylin agonist.

Kolterman ('220) describes the use of an amylin agonist for treating type II diabetes mellitus and demonstrates that administration of an amylin agonist significantly reduces postprandial plasma glucose concentrations in patients with type II diabetes mellitus. Kolterman ('220) does not teach the use of an amylin or an amylin agonist for treating obesity or demonstrate a reduction in body weight in those patients administered an amylin or an amylin agonist. Kolterman ('220) is silent with regard to the effect of an amylin or an amylin agonist on body weight.

This rejection is based on alleged inherent anticipation by Kolterman ('220). The Examiner asserts that the method of Kolterman ('220) is the same as the claimed method "based upon the fact that the method step, the compound administered, the amount of the compound administered, and the route by which the compound is administered, and the human patient population to which the compound is administered, are overlapping in the two methods." Office Action, section 48, page 27. Applicants disagree with this assertion.

An "overlap" in the two methods is not the standard to establish inherent anticipation. Applicants respectfully note that the "fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993); emphasis in original. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the references, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson* 169 F.3d 743, 745 (Fed. Cir. 1999); emphasis added.

The courts have held that the phrase "in need thereof" is meaningful, and that "the claims' recitation of a patient or a human 'in need' gives life and meaning to the preambles' statement of purpose." *Jansen v. Rexall Sundown, Inc.* 342 F.3d 1329, 1333 (Fed. Cir. 2003).

Thus, Kolterman ('220) cannot render unpatentable by inherency the subject population of the claimed invention.

The patient population of Kolterman ('220) is not necessarily the same as the claimed subject, *i.e.*, a subject in need of a method of treating obesity. Obesity is indeed a common characteristic of patients with type 2 diabetes mellitus. However, a reference which teaches treating type 2 diabetic patients with an amylin or amylin agonist does not necessarily teach treating patients with obesity as claimed.

To support inherent anticipation of the claimed methods by Kolterman ('220), the Examiner relies on the statement in the specification that obesity is a characteristic of "most patients with Type II diabetes mellitus" and the statement in Tsanev that "up to 90% of diabetic patients are intrinsically obese." Office Action, section 31B, page 13 and section 48, page 27. Applicants respectfully point out that "most patients" and "up to 90% of diabetic patients" do not show that all patients with type II diabetes are obese. In fact, these statements indicate that not all patients with type II diabetes are obese and, thus, do not support inherent anticipation by Kolterman ('220).

Accordingly, a reference which teaches treating type II diabetic patients with an amylin or amylin agonist does not necessarily teach treating patient with obesity. Thus, the claimed invention cannot be recognized by one skilled in the art as inherently taught in the cited reference.

Applicants respectfully submit that Kolterman ('220) does not explicitly or inherently teach each element of the claimed methods. Thus, the cited reference does not anticipate the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §102(a).

In sum, Applicants respectfully submit that the cited references do not anticipate the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §102.

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CONCLUSION

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the examiner is encouraged to contact Applicants' representative at the telephone number below.

No additional fees are believed due for this submission. However, if a fee is due, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, to Applicants' Deposit Account No. 010535 referencing Docket No. 226/104 US. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Applicant's Deposit Account No. 010535.

Date: December 1, 2006

Respectfully submitted,

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